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INTERNATIONAL SEARCHING AUTHORITY

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2006/045172

International filing date (day/month/year)
22.11.2006

Priority date (day/month/year)
23.11.2005

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/88 A61F2/46

Applicant
CONFORMIS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2006/045172

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 29-52

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 29-52

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2006/045172

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>5,13,15,16,24-25</u>
	No: Claims	<u>1-4,6-12,14,17-23,26-28,53-58</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-28,53-58</u>
Industrial applicability (IA)	Yes: Claims	<u>1-28,53-58</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III.

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

Claims 29-52 refer to methods of grasping an implant. This action is only disclosed in combination with the insertion of the implant into the human body and forms part of a method for treatment of the human or animal body by surgery.

Therefore no search has been performed for claims 29-52 (Article 34(4)(a) PCT).

Re Item V.

1 Reference is made to the following documents:

D1 : US 5 591 165 A (JACKSON ROGER P [US]) 7 January 1997 (1997-01-07)

D2 : FR 2 795 945 A1 (SCIENT X [FR]) 12 January 2001 (2001-01-12)

2 INDEPENDENT CLAIMS 1, 11, 21, 53 and 56

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (the references in parentheses applying to this document):

A device for grasping an implant (figs. 15a, 15b), the implant for use in a joint and having a first and second surface (fig. 16), at least one of the first and second surfaces being non-planar, the grasper device comprising:

a first grasping element (72) including a first grasping surface substantially conforming to the first surface of the implant;

a second grasping element (69) including a second grasping surface substantially conforming to the second surface of the implant;

wherein at least one of the first grasping element and the second grasping element can be moved to grasp the implant, such that the first grasping surface contacts the first surface of the implant and the second grasping surface contacts the second surface of the implant (col. 15, l. 14-25).

2.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 11 is not new in the sense of Article 33(2) PCT.

Document D2 discloses (the references in parentheses applying to this

document):

A surgical instrument (fig. 4) for grasping an implant having a first and second surface, the implant for use in a joint (intervertebral joint), at least one of the first and second surfaces (2, 20) being non-planar (fig. 1), the surgical instrument comprising:

- a first grasping element (16, 21);
- a second grasping element (16, 21);

wherein at least one of the first grasping element and the second grasping element can be moved to grasp the implant such that the first grasping element contacts the first surface of the implant and the second grasping element contacts the second surface of the implant, and wherein at least one of the first grasping element and the second grasping element is made of a pliable material (p. 7, l. 9-14).

- 2.3 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 21 is not new in the sense of Article 33(2) PCT.

Document D1 discloses:

An implant system comprising:

- an implant (fig. 15) having first and second surfaces facing in substantially opposite directions, the first surface including a first indentation; and
 - an implant grasper (figs. 15a, 15b) for gripping the implant, the implant grasper including a first grasping element and a second grasping element;
- wherein the first indentation (73) has peripheral walls that prevent rotation of the implant when the first grasping element (77) is received by the first indentation and the second grasping element of the implant grasper contacts the second surface to grasp the implant.

- 2.4 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 53 is not new in the sense of Article 33(2) PCT. Document D1 discloses a set comprising the grasping device according to claim 1 and the implant (fig. 16).

- 2.5 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 56 is not new in the sense of Article 33(2) PCT. Document D2 discloses a set comprising the surgical instrument according to claim 11 and the implant (fig. 1).

**WRITTEN OPINION OF THE
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AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2006/045172

7 DEPENDENT CLAIMS 2-10, 12-20, 22-28, 54, 55, 57, 58

Dependent claims 2-10, 12-20, 22-28, 54, 55, 57, 58 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).